UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC., *et al.*, **Plaintiffs,** **v.** **WATSON PHARMACEUTICALS, INC., *et al.*,** **Defendants.**	**Civil Action No. 09-5421(GEB) (TJB)** **Motion Returnable: January 4, 2010**
WEST-WARD PHARMACEUTICAL CORP., **Counterclaimant,** **v.** **MUTUAL PHARMACEUTICAL COMPANY, INC., *et al.*,** **Counterdefendants.**	

DEFENDANT-COUNTERCLAIMANT WEST-WARD PHARMACEUTICAL CORP'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS

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PRELIMINARY STATEMENT

In their response brief [Docket 199], Plaintiffs acknowledge that their lawsuit is premised on issues over which FDA has enforcement authority, but claim that this Court should not defer to FDA on these issues because FDA has already made its judgment calls. According to the Plaintiffs, there is no chance that this Court will render a ruling inconsistent with FDA's judgment because FDA's involvement is over; "FDA has made a final determination on the issue." [Docket 199 at 1]. "FDA has already determined the label requirements" for the products. [Docket 199 at 1].

Plaintiffs' arguments do not square with the allegations that they are pursuing in this lawsuit. Their lawsuit boils down to two essential claims:

(1) Defendants are misleading the pharmaceutical industry about the approval status of their products by keeping their products listed in databases that list pharmaceutical products ("false approval claims"); and

(2) Defendants are misleading the pharmaceutical industry about the safety of their products by not using the same FDA-approved labels that Plaintiffs are using ("false labeling claims").

These allegations are infected with FDA jurisdictional issues, and are far from resolved at the Agency. FDA jurisdiction over products such as these, which have been on the market since the 19th century without formal approval, is doubtful. [Docket 143 at 3-8]. There is a very real prospect for inconsistent results if Defendants are allowed to pursue their "false approval" claims when FDA has not even decided whether approval is required.

In like manner, there is a very real prospect for inconsistent results if Defendants are allowed to pursue their "false labeling" claims. No one knows what sort of label FDA would demand were the Defendants to solicit FDA approval for their products. Labels elements such as warnings and contraindications are extremely sensitive to the intended use of the product, and Defendants' products are already labeled with a different indication than Plaintiffs – for the

prevention of gout flares instead of the *treatment* of gout flares. [Docket 143 at 5]. The Plaintiffs argue that the Defendants are misrepresenting the safety of their product by using a different label than theirs, but this argument presupposes that the Defendants would seek approval for the same indications, and that their labeling is the only way to truthfully present the safety of oral colchicine. If this Court gets into the drug labeling business, there is a very real prospect of conflicting decisions by this Court and FDA that counsels for deference to FDA in this instance.

LEGAL ARGUMENT

A. Plaintiffs' Claims Must be Dismissed Because Plaintiffs Fail to Point to Any Affirmative Statements in West-Ward's Advertising Declaring that that West-Ward Obtained FDA-Approval.

The potential for conflicting decisions from this Court and FDA are what make this case comparable to *Eli Lilly*. As the Plaintiffs acknowledge, the false advertising claims in *Eli Lilly* were "all based on allegations that defendants falsely implied or represented that they properly obtained FDA approval of their drug products." *See Eli Lilly & Co v. Roussel Corp.*, 23 F. Supp. 2d 460, 478 (D.N.J. 1998) (emphasis supplied); *see also* [Docket 199 at 2]. While Plaintiffs' claims in this case are based on allegations that the Defendants falsely implied that they had obtained FDA approval for their colchicine products, this insignificant factual distinction is irrelevant to the clear rule of law delivered by the Court in *Eli Lilly*. The dismissal of the plaintiffs' claims in *Eli Lilly* was based on the Court's finding that the plaintiff "failed to point to any statements or representation in defendants' advertising which declared that they obtained 'proper FDA approval.'" *Eli Lilly* at 478. The Court in *Eli Lilly* noted that, in order to survive a motion to dismiss, the plaintiff must identify "'words or phrases which suggested 'positively' that the FDA had approved [defendant's] drugs.'" *Id.* (citation omitted)

Eli Lilly stands for the proposition that a plaintiff cannot sustain a false advertising claim with regard to the FDA approval requirements of a drug based on "implications" drawn from the defendants' advertising; the state of the law is simply too

complex and FDA's jurisdiction too pervasive to imply any representations; the plaintiff must point to an affirmative statement or representation in the defendant's advertising whereby the defendant falsely declared that it had obtained FDA approval. Otherwise, the Court would run a very real risk that FDA might reach a different result concerning its jurisdictional reach. Notably, the Court in *Eli Lilly* concluded that "[t]he Lanham Act does not provide a right of action with respect to implied representations that defendants obtained FDA approval . . . ." *Id.* at 479-80. In the present case, because the Plaintiffs have "failed to point to any statements or representation in defendants' advertising which declared that they obtained '[] FDA approval,'" Plaintiffs' claims must be dismissed.

B. The *Bracco* Case Has No Bearing on the Legal Issues in the Present Case.

In their response brief, Plaintiffs take the position that "[t]he case that sheds the most light on the present action is not *Eli Lilly and Co.*, but rather *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384 (D.N.J. 2009)." [Docket 199 at 4.] Plaintiffs misapply the conclusions of law in *Bracco*. The Court in *Bracco* began its analysis with the rule that "the Lanham Act prohibits only those false or misleading statements made in 'commercial advertising [and] promotion.'" *Id.* at 455 (quoting *Gordon & Breach Science Publishers v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1533 (S.D.N.Y.1994)). Therefore, the false advertising analysis in *Bracco* was comprised of two steps: (1) whether the defendant made any "false or misleading statements;" and, if so, (2) whether those false statements were made in "commercial" speech. The Court in *Bracco* glossed over the first prong of this analysis – whether the alleged advertising contained any "false or misleading statements" – and focused on whether the affirmative statements at issue constituted "commercial" speech. The Court ultimately concluded that the published scientific research at issue in *Bracco* was not commercial speech, and thus, "it would be inappropriate to 'inquire into the validity of ... scientific theories' which are not commercial speech . . . ." The risk of an inconsistent judgment with FDA was not an issue because the entire focus was on the commercial speech element.

In the present case, the definition of "commercial" speech has no bearing on West-Ward's Motion, as Plaintiffs are unable to overcome the first prong of the *Bracco* analysis. Namely, Plaintiffs have failed to point to a single "false or misleading statement" contained in West-Ward's advertising, or one that is not encumbered with risk to FDA's concomitant decision making authority. The holding from *Bracco* sheds no light on this issue, which, coincidentally, is analyzed in detail by the Court in *Eli Lilly*. Furthermore, the cases cited by the Defendants in their prior briefing, including *Mylan Labs, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), reached the same conclusion in the context of pharmaceutical litigation – absent an express, affirmative representation of FDA-approval, Plaintiffs' false advertising claims must be dismissed.

CONCLUSION

For the reasons stated herein, and in all of the prior submissions in support of Defendants' Motion to Dismiss and Motion for Judgment on the Pleadings, West-Ward respectfully requests that its Motion for Judgment on the Pleadings be granted and that this action be dismissed.

Respectfully submitted,

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